

MAR - 4 2010

**SPECIAL 510(K) SUMMARY****1. GENERAL INFORMATION**

|                                    |   |
|------------------------------------|---|
| Trade Name                         | PASS LP Spinal System   |
| Common Name                        | <ul style="list-style-type: none"> <li>✓ Posterior pedicle screw system</li> <li>✓ Hooks</li> <li>✓ Sacral plate</li> <li>✓ Iliac screw</li> </ul>  |
| Classification Name                | <ul style="list-style-type: none"> <li>✓ orthosis, spinal pedicle fixation per MNI 888.3070</li> <li>✓ orthosis, spondylolisthesis spinal fixation per MNH 888.3070</li> <li>✓ appliance, fixation, spinal interlaminar per KWP 888.3050</li> </ul> |
| Class                              | Class II  |
| Product Code                       | MNI / MNH / KWP   |
| CFR section                        | 888.3070 / 888.3050   |
| Device panel                       | Orthopedic  |
| Legally marketed predicate devices | PASS LP Spinal System (MEDICREA) = K080099<br>QUANTUM Spinal System (PIONEER) = K080518   |
| Reason for Special 510(k)          | Product range extension and additional components   |
| Submitter                          | MEDICREA® Technologies<br>Z.I. Chef de Baie<br>17000 La Rochelle, France  |
| Contact                            | J.D. Webb<br>1001 Oakwood Blvd<br>Round Rock, TX 78681<br>512-388-0199<br>E-Mail: ortho.medix@sbcglobal.net   |

**2. PREDICATE DEVICE DESCRIPTION**

The Medicea PASS LP Spinal System consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink members. It can be used for single or multiple level fixations. All components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

**3. DESCRIPTION OF DEVICE MODIFICATION**

The purpose of this submission is to make modifications to the PASS LP Spinal System.

**4. INTENDED USE**

The PASS LP Spinal System includes a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.



The PASS LP Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also includes hooks, rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

#### **5. PERFORMANCE DATA**

When applicable, the tests performed on the additional components (according to ASTM F1717 or ASTM F1798) or the finite element analysis, indicate that the products are as mechanically sound as other devices commercially available.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

MAR - 4 2010

Medicrea Technologies  
% The Orthomedix Group, Inc.  
Mr. J.D. Webb  
1001 Oakwood Blvd.  
Round Rock, Texas 78681

Re: K100297  
Trade/Device Name: PASS LP Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, MNH, KWP  
Dated: January 29, 2010  
Received: February 5, 2010

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – Mr. J.D. Webb

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K100297

Device Name: PASS LP Spinal System

### PASS LP Spinal System

#### Indications for Use

The PASS LP Spinal System includes a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.

The PASS LP Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also includes hooks, rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K100297

Pg 1 of 1